**CABRINI LOWER RISK NON-HREC REVIEW APPLICATION FORM**

|  |
| --- |
| *Considerations before you complete this form:*   * *Have you completed the Cabrini Research Risk Assessment Checklist and confirmed the correct review pathway with the Cabrini Research Governance Office (CRGO)?* * *Ensure you have read the CRGO handbook.* * *This form is only to be used for lower risk projects run solely at Cabrini (i.e. does not involve external collaboration).* * *Quality Assurance (QA) - Only use this form for QA projects if you intend to publish your results / outcomes. Note all QA will be reviewed as lower risk research.* * *State N/A for any questions or sections that do not apply to your project.* * *Ensure the application has been signed by all investigators prior to submission.* * *Send your complete submission to* [*researchgovernance@cabrini.com.au*](mailto:researchgovernance@cabrini.com.au) *or call our team on Tel: 03 9508 3412 with queries.* * *For projects that have received HREC approval and are seeking Cabrini Governance Approval, please use the* ***Cabrini Site Specific Assessment (SSA - Governance Review) Application*** *and do not proceed with using this form.* * ***CRGO cannot provide retrospective ethical and governance review of research or QA work that has already occurred.*** |

**SECTION 1 – ADMINISTRATIVE INFORMATION**

1. **Project Title**

|  |  |
| --- | --- |
| Project full title |  |
| Project short title |  |
|  |  |

1. **Principal Investigator**

|  |  |
| --- | --- |
| Title & Name |  |
| Position |  |
| Department & Campus |  |
| Affiliate Institution |  |
| Cabrini affiliation | *Students cannot be principal investigators. Refer to CRGO Handbook for PI eligibility.*  Cabrini Employee – Are they on a fixed term contract Yes  No  Fixed Term Contract Expiry Date: / /  Cabrini Visiting Medical Officer (VMO) |
| Qualifications |  |
| Project Tasks |  |
| Mailing address |  |
| Phone |  |
| Email | *professional affiliation:* |
| Credential Documents | *All are mandatory*  CV  GCP Expiry:  Research Integrity training Expiry: |

1. **Additional Investigators /Study Coordinators/Contact Person *(copy and paste this box as needed)***

|  |  |
| --- | --- |
| Title & Name |  |
| Position & role in project |  |
| Department & Campus |  |
| Affiliate Institution |  |
| Cabrini affiliation | Cabrini Employee – Are they on a fixed term contract Yes  No  Fixed Term Contract Expiry Date: / /  Cabrini Visiting Medical Officer (VMO)  Other (specify): |
| Qualifications |  |
| Project Tasks |  |
| Mailing address |  |
| Phone |  |
| Email |  |
| Credential Documents | CV  GCP Expiry:  Research Integrity training Expiry:  *CV and GCP are mandatory. Research Integrity is recommended.* |

1. **Student Researcher**

|  |  |
| --- | --- |
| Title and Name |  |
| Position & role in project |  |
| Department & Campus |  |
| Tertiary Institution |  |
| Course & Placement Details | Name of Course:  Is the student on clinical placement? Yes  No  Duration and dates of Clinical Placement:  Does the research project contribute to the course/qualification? Yes  No  Specify:  Is there a Clinical Placement Agreement or other agreement in place between the student’s tertiary institution and Cabrini that covers their involvement in research?  Yes  No  Specify: |
| Cabrini affiliation | Cabrini Employee – Are they on a fixed term contract? Yes  No  Fixed Term Contract Expiry Date: / /  Cabrini Visiting Medical Officer (VMO)  Other (specify): |
| Project Tasks |  |
| Mailing address |  |
| Phone |  |
| Email |  |
| Credential Documents | CV  GCP Expiry:  Research Integrity training Expiry:  *CV and GCP are mandatory. Research Integrity is recommended.* |

1. **Fee Payment Details**

|  |  |
| --- | --- |
| ***If the project is billable, an invoice for submission fees will be sent during the review process, and subsequent invoices will be issued for amendments. Refer to the*** [***CRGO Fee Schedule***](https://www.cabrini.com.au/app/uploads/5891_80419_21Dec2023110634_Cabrini-Research-Governance-Fees-Table-1-January-2024-final.pdf)***. Provide details for the person responsible for payments below:*** | |
| Name |  |
| Position / Title |  |
| Organisation |  |
| Address |  |
| Contact phone number |  |
| Contact email |  |

**SECTION 2 – RESOURCES**

1. **Sponsorship / Other Funding and Staffing**

|  |  |
| --- | --- |
| Funding | How is this project being financed? |
| Funding Details | *If funded by an internal or external grant, provide a copy of the offer letter or funding agreement and a Cabrini finance reference code if already assigned, otherwise a finance reference code will be arranged.*  Name of Funder & Grant:  Total Amount Awarded: $  Grant Duration:  Funding Agreement or Offer Letter provided: ☐ Yes ☐ No |
| Budget | Project Budget *Alternately can be attached as a separate document.* |
| Cabrini Contributions & Support | Is Cabrini expected to provide any:   * Funding? Yes  No  Specify: * Staff time? Yes  No  Specify: * Facilities? Yes  No  Specify:   Has a Project Resourcing & Costing Template been provided? Yes  No |
| Declaration of Interests | *State any conflict of interest, including financial or other interest or affiliation that bears on this project.* |

**SECTION 3 – PROJECT SUMMARY**

1. **Project Summary**

|  |  |
| --- | --- |
| Lay Summary | *Give a brief plain language summary (max. 250 words) of the project including aim/hypothesis and rationale relating to current literature. The summary should be in plain (grade 8 level) language suitable to be read and understood by laypersons.* |
| Protocol | Version # and date:  Is the protocol included in the submission pack? Yes  No |

**SECTION 4 – PROJECT DETAILS**

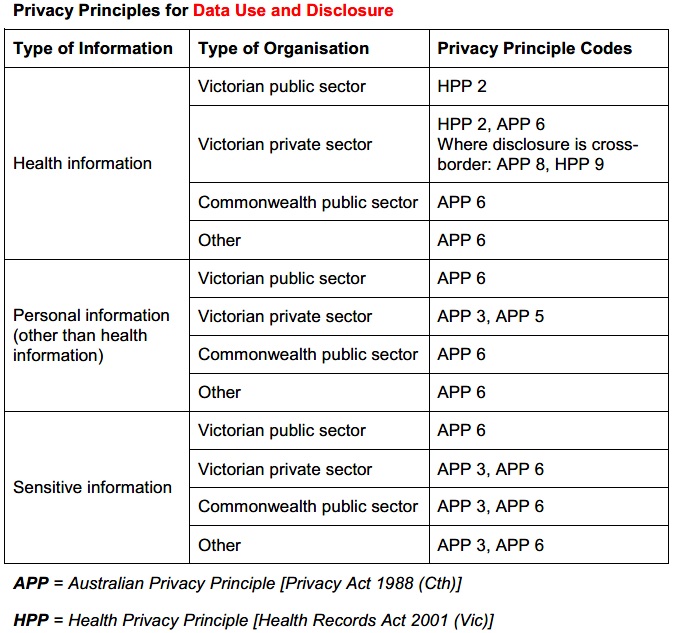
1. **Project Details**

|  |  |
| --- | --- |
| Project Category | Clinical Research  Research – Other\* (health services research, social science)  \*Other (specify):  Quality Assurance (QA) – specify type:  Clinical Audit – Prospective  Clinical Audit – Retrospective  Evaluation Activity  QA Other (specify): |
| Research Category | *E.g. oncology, cardiology, urology, exercise, gynaecology, nursing, ICU, anaesthetics, mental health, physiotherapy etc* |
| Duration | Proposed start date:  Expected completion date: |
| Research Location(s) | *State the Cabrini campuses where research will be conducted.* |
| Cabrini Mission | Is there anything in this project that may conflict with [Cabrini Health’s Mission and Values](https://www.cabrini.com.au/about-cabrini/our-mission-and-heritage/)? Yes  No |
| Catholic Health | Is there anything in the project that may contravene Catholic Health Australia’s Code of Ethical Standards for research *(e.g. references to contraception or sterilisation, methods of addressing infertility, assisted reproductive therapy, voluntary assisted dying)?*  Yes  No  If yes, specify: |
| Peer Review | *Peer review is an independent assessment of your proposal by experts or people with similar competencies in your field. It is an important source of feedback to ensure your project is optimally designed and articulated to answer the research question or achieve the project aims.*  Has this study received peer review? Who conducted the review? Were recommendations adopted? Provide evidence. If no peer review was sought, advise why. |
| Consumer Consultation | *If you obtained consumer input for this project, please outline how they contributed to the study design and review of the consent process. If you were unable to involve consumers in the development of your project and would like to have their feedback, please note this in your response and we will arrange for your project to be reviewed and feedback provided by a Cabrini Research consumer.* |
| Academic Head of Dept. approval | Was approval sought? *Provide evidence or obtain their signature at the end of this form.*  If not sought, advise why. |
| Craft Group Lead / Clinical Head of Dept approval | Was approval sought? *Provide evidence or obtain their signature at the end of this form.*  If not sought, advise why. |
| Recruitment | Can this study be undertaken without using human participants?*Refer to the* [*National Statement*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)*’s definition of ‘human participation in research’ which includes involvement in surveys / interviews / focus groups, observation, researcher access to a participant’s personal documents and information.* Yes  No  Number of Participants:  Age Range:  Gender:  Method/Source of recruitment *e.g. inpatient, researcher rooms, nursing staff, medical records, hospital or other databases*:  What access permissions will be sought?  Inclusion Criteria:  Exclusion Criteria: |
| Consent | Will you be seeking consent from all participants of the project (including participants whose records are to be reviewed)? Yes  No  If No, explain why not?  How will initial contact be made?  Will each participant be capable of giving informed consent? Yes  No  What type of consent will be sought? *e.g. Written / Explicit consent, implied, verbal*  *Describe the process for obtaining consent including when and how the explanation of the project will be given to potential participants, who will conduct the consenting process and how they will ensure that participants are able to make a free and informed decision to participate.*  How will consent be recorded?  Will you be seeking consent for use of the collected information for this research project only (specific consent), future research related to this project (extended consent) or any future research (unspecified consent)?  Will any special relationship exist between the recruiter and the participants? *e.g. doctor/patient, employer/employee, supervisor/worker/student*. If yes, how will this be managed?  How is it clearly documented that participants may withdraw from the project at any time?  *Provide a copy of the Participant Information & Consent Form (PICF) or Participant Information Sheet (PIS) if applicable.* |
| Demands on Participants | *Describe all the procedures to be conducted with participants which are specifically for this project (outside of standard of care). Explain the number of visits, surveys / questionnaires, interviews, time commitment and burden.* |

**SECTION 5 – DATA MANAGEMENT**

1. **Data Collection and Use**

|  |  |
| --- | --- |
| Ensure compliance with the [*Health Records Act*](https://www2.health.vic.gov.au/about/legislation/health-records-act) (Vic) (2001), the Privacy Act 1988, the [*Australian Code for the Responsible Conduct of Research*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018) (NHMRC, 2018) and the [*Cabrini Research Data Management, Access and Sharing Policy*](https://www.cabrini.com.au/app/uploads/Cabrini-research-data-management-access-sharing-policy-Aug2024.pdf)*. Refer to* ‘Privacy Principles for Data Use and Disclosure’ table | |
| Types of data to be collected | Prospective collection of data  Existing records or data |
| Types of information to be collected and/or used | Personal information  Health information  Sensitive information |
| Outline the data that will be collected / used / disclosed |  |
| Outline the process for data collection / storage |  |
| Medical Records | If access to medical records is required, has permission and a quote (if applicable) from Health Information Services been sought? Yes  No  *Provide evidence* |
| In what form will data be accessed or collected? | Identifiable  Re-identifiable  Non-identifiable  Note that access to identifiable records for the purpose of extracting non-identifiable data constitutes 'use' and 'disclosure' of identifiable data even if such data will not be 'collected'. *Refer to* [*Chapter 3.1 National Statement 2023*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) *and* [*Cabrini Research Data Management, Access and Sharing Policy*](https://www.cabrini.com.au/app/uploads/Cabrini-research-data-management-access-sharing-policy-Aug2024.pdf) *for information regarding data identifiability in research.* |
| In what form will data be used and stored? | Identifiable  Re-identifiable  Non-identifiable |
| Privacy Principles | For the information that will be used, select the Privacy Principles from the table below that will apply:  Delete ‘Privacy Principles for Data Use and Disclosure’ table once relevant principles are stated. |
| Master Key Access | Who has authority within the project team to re-identify coded data? |
| Routine Access | If project team members will be accessing or using identifiable participant personal / personal health information, do they have routine access to the data? Yes  No |
| Honorary Researcher Appointment (HRA) | If the team members do not have routine access to the data, do they require HRAs? |
| Duration of data storage | *State the duration of data storage after completion of the project* |
| Location of data storage |  |
| Post Storage Handling | What will happen to the data at the end of the retention period (e.g. how will it be destroyed)? |
| ***Dissemination of Project Results*** | |
| How will the findings of this work be disseminated (besides research governance reporting)? | Peer-Reviewed Journal  Conference Presentation - Oral  Conference Presentation - Poster  Final report to Department Head  Final report to Cabrini Group Executive  Final report to another leadership group  Staff In-service  Internal presentation to craft group or department  Internal Committee presentation  Submission of report or presentation to University  Other - Specify: |
| Data Format for Reporting / Disclosure | In what format (scope of identifiability) will data be disclosed in any of the above-stated research outputs? |
| Results to Participants | Will results be provided to participants and in what form? If not, provide a justification. |



**SECTION 6 – SUPPORTING DOCUMENTS**

|  |  |
| --- | --- |
| Have you included all the required documents in your submission? | CV, GCP & Research Integrity training certificates  Proof of funding letter  Protocol  PICF / PIS  Advertising Materials  Data Minimum Dataset / List of data variables  Case report form  Data Management Plan  Surveys and Questionnaires  Focus group questions, interview schedule  Letter of support  Peer review  Medical Practitioner Indemnity Insurance Certificate  Other (specify): |

**SECTION 7 – DECLARATIONS**

|  |
| --- |
| **Principal Investigator Declaration** |
| **I certify that:**   * The information in this form is truthful and accurate to the best of my knowledge and belief, and I take full responsibility for this project at Cabrini Health. * I will only start this research project after obtaining authorisation from the Cabrini Research Governance Office (CRGO). * I accept responsibility for the conduct of this research project according to the principles of the *National Statement on Ethical Conduct in Human Research (NHMRC 2023)*. * I will conduct this research in accordance with relevant legislation and regulations. * I have read all relevant Cabrini Research policies and guidelines applicable to this project, including but not limited to the Monitoring of Research Policy, Research Integrity and Misconduct Policy, Authorship and Publication in Research Policy and Data Management, Sharing and Access Policy. * I have consulted with other departments should they be impacted by this project. * All project team members and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training to fulfil their role in this project. * I will conduct this research project in accordance with the ethical and governance requirements of Cabrini Research. * I will adhere to the conditions of authorisation stipulated by the CRGO and will comply with their monitoring requirements. * I will discontinue the research if the CRGO withdraws authorisation. * I will inform the CRGO if the research project ceases before the expected date. * I understand and agree that study files, documents, research records and data may be subject to inspection by the CRGO for audit and monitoring purposes. * I understand that information relating to this research and about me as a researcher will be held by the CRGO. I understand that this information will be used for reporting purposes and managed according to the principles established in the *Privacy Act 1988* (Cth) and relevant laws in the States and Territories of Australia. * No data capable of identifying a person will be published. * Additional information about the project, for the purposes of ensuring patient privacy and ethical conduct, will be provided to CRGO upon request. * I will also adhere to Cabrini Health’s Mission Statement, and the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia. * CRGO will be notified in writing if any changes to the project are proposed that would impact on ethical considerations. I confirm no changes will occur until approval is granted by CRGO.   Name:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

|  |
| --- |
| **Associate Investigator / Student Investigator / Study Coordinator Declaration** |
| **I certify that:**   * The information in this form is truthful and accurate to the best of my knowledge and belief. * (For students) I will operate under the direct supervision of the Principal Investigator. * I will conduct this research in accordance with relevant legislation and regulations. * I have read all relevant Cabrini Research policies and guidelines applicable to this project, including but not limited to the Monitoring of Research Policy, Research Integrity and Misconduct Policy, Authorship and Publication in Research Policy and Data Management, Sharing and Access Policy. * I have consulted with other departments should they be impacted by this project. * I will conduct this research project in accordance with the ethical and governance requirements of Cabrini Research. * I will adhere to the conditions of authorisation stipulated by the CRGO and will comply with their monitoring requirements. * I understand and agree that study files, documents, research records and data may be subject to inspection by the CRGO for audit and monitoring purposes. * I understand that information relating to this research and about me as a researcher will be held by the CRGO. I understand that this information will be used for reporting purposes and managed according to the principles established in the *Privacy Act 1988* (Cth) and relevant laws in the States and Territories of Australia. * No data capable of identifying a person will be published. * Additional information about the project, for the purposes of ensuring patient privacy and ethical conduct, will be provided to CRGO upon request. * I will also adhere to Cabrini Health’s Mission Statement, and the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia.   *Add as many associate investigator / student investigator signatures below as required*  Name:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:  Name:  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: |

|  |
| --- |
| **Academic Head of Department Declaration** |
| *• An investigator must* ***not*** *approve their own research on behalf of their department. If an investigator is also the Academic Head of Department, the study will be assessed by the multidisciplinary Cabrini Research Governance Committee.*  *• If an Academic Head of Department does not exist for your area of research, the study will be assessed by the multidisciplinary Cabrini Research Governance Committee.*  **I certify that:**   * I have read the research project application named above. * The research aligns with Cabrini’s research strategy, does not duplicate existing research, and fosters collaborative rather than siloed research (where applicable). * I have discussed this research project, and the resource implications for this department, with the Principal Investigator. There are suitable and adequate facilities and resources for the research project to be conducted at this site. I support this research project being carried out using such resources. * All investigators/students from my department involved in the research project have the skills, training and experience necessary to undertake their role. * I undertake to be the contact point for escalation of any issues (e.g. audit findings, ethical concerns, complaints) that cannot be resolved with the Principal Investigator, and will oversee the resolution of such issues.   Name: Position:  Signature: Date: |

|  |
| --- |
| **Craft Group Lead or Clinical Head of Department Declaration** |
| *• A Head of Department may delegate responsibility to an appropriate staff member.*  *• An investigator must* ***not*** *approve their own research on behalf of their department. If an investigator is also Craft Group Lead or Clinical Head of Department, approval must be sought from the person to whom they report.*  **I certify that:**   * I have read the research project application named above. * I have discussed this research project, and the resource implications for this department, with the Principal Investigator. There are suitable and adequate facilities and resources for the research project to be conducted at this site. I support this research project being carried out using such resources. * All investigators/students from my department involved in the research project have the skills, training and experience necessary to undertake their role. * I undertake to be the contact point for escalation of any issues (e.g. audit findings, ethical concerns, complaints) that cannot be resolved with the Principal Investigator, and will oversee the resolution of such issues.   Name: Position:  Signature: Date: |

*This application is informed by the*

[*NHMRC’s National Statement on Ethical Conduct in Human Research 2023*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

[*Ethical Considerations in Quality Assurance and Evaluation Activities 2014*](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities)